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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,410	12/12/2000	Burkhard Goke	0206-UTL-9	8826

7590 04/20/2005

## ARNOLD & PORTER

Attn: IP Docketing Department, Room 1126B  
555 Twelfth Street, NW  
Washington, DC 20004-1206

EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/719,410	<b>Applicant(s)</b> GOKE ET AL.	
	<b>Examiner</b> Abdel A. Mohamed	<b>Art Unit</b> 1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 55-58.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 10-38, 41, 44-46 and 48-54.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

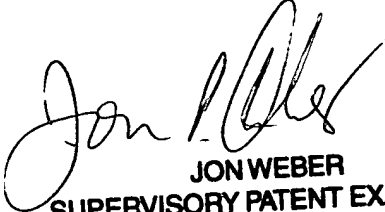
#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): filed 02/22/05
13. ☐ Other: \_\_\_\_\_.

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Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 102(b) and 35 U.S.C. 112, first paragraph for written description.

Continuation of 11 does NOT place the application in condition for allowance because: The rejection under 35 U.S.C. 112, first paragraph for new matter over claims 10-38, 41, 44-46 and 48-54 is maintained. Applicant's arguments filed 3/28/05 have been fully considered but they are not persuasive. Applicant argues that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, i.e., to ensure that the inventors actually invented what is claimed and for support cites various case laws (See e.g., page 14 of the remark filed 3/28/05). Further, Applicant argues that the specification and claims as originally filed adequately support the amended claim language "who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM)" See e.g., specification at page 1, lines 15 to page 2, line 3; page 3, lines 3-10; page 4, lines 1-8; and page 6, lines 1-9; particularly, page 1, line 22 to page 2, line 3, IGT is a distinct condition which may or may not develop into NIDDM. Applicant's instant claims merely clarify that the methods are directed to treating the condition of IGT. Applicant concludes by stating that based on the examples in the specification, the skilled artisan would recognize that IGT subjects had not been diagnosed with NIDDM, or else they would not have been included in the IGT group but instead placed in the NIDDM group. Accordingly, it is contemplated at the time of the filing as one subject population the treatment of subjects with IGT whose inability to control glucose had not advanced to the point where those subjects were diagnosed with NIDDM. Thus, the specification states the need for a therapy to treat IGT, while acknowledging that studies exist for the application of GLP-1 in case of NIDDM is unpersuasive. Contrary to Applicants' arguments, the above citation or anywhere in the instant specification have no support for the treatment of IGT in a patient who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM). The above citations disclosed by Applicant discuss about the prevalence and characterization of IGT and not the negative limitation claimed by Applicant (i.e., who has not been diagnosed with NIDDM). Thus, Applicant's specification demonstrates no intent or concept to include or contemplate the negative limitation of "who has not been diagnosed with NIDDM": The negative limitation is a new concept having no support in the instant specification. Therefore, the rejection under 35 U.S.C. 112, first paragraph for new matter for claims 10-38, 41, 44-46 and 48-54 is maintained for the reasons of record and for the reasons stated above.

  
JON WEBER  
SUPERVISORY PATENT EXAMINER